

most nearly connected, to make and/or use the invention. Particularly, the Examiner indicates that no examples in this specification show any data for lowering cholesterol or triglycerides in the blood stream of a subject. The Applicant respectfully traverses this objection. The Applicant submits that it is not required under United States law that there be data in the specification to show the cholesterol and triglyceride lowering effects of the nutritional supplement. The Applicant has made the statement, for example, on page 3 at lines 6 to 9, that the nutritional supplement comprising a sterol and an omega-3 fatty acid will have the effect of lowering cholesterol and triglyceride levels. In the absence of any specific and supported reasoning from the Examiner, this statement must be accepted on its face. Furthermore, the specification from page 11, at line 9 to line 19, describes how the nutritional supplement may be included in food stuffs so that one skilled in the art understands how the nutritional supplement may be utilized in practice. The specification from page 7, at line 6, to page 8, at line 15, provides guidance as to the amount of the nutritional supplement which may be used. In the Applicant's response of April 12, 2001, a Declaration of Dr. H. Stephen Ewart was filed attesting to the efficacy of the subject invention, i.e., the cholesterol and triglyceride lowering effect in the blood of an animal. Therefore, the Applicant respectfully submits that the pending claims are fully enabled by the description and that one skilled in the art can make complete and full use of the invention as claimed.

Additionally, the Applicant notes that claim 38 submitted with the Request for Continuing the Examination does not specify that the composition is "for lowering cholesterol and triglyceride levels in the blood stream of a subject". Therefore, it is not clear why the Examiner has

objected to claim 38 under the rationale specified by the Examiner in the recent Office Action.

The Examiner has objected to claims 1, 5, to 11, and 30 and 39 as being unpatentable over Miettinen et al. in view of Alexander et al.

The Examiner has stated that Alexander (hereinafter Leaf) teaches n-3 fatty acids for lowering LDL cholesterol, and may be combined with Miettinen because they are from the same field. Leaf teaches the use of n-3 fatty acids (alone) in lowering cholesterol levels. There is no suggestion that addition of n-3 fatty acids to a sterol ester mixture would be effective. Miettinen teaches the combination of β -sitosterol with rapeseed oil; there is no suggestion of combination with other fatty acids or fatty acid mixtures. At best it might be "obvious to try" such combination put forward by the Examiner, but that is not the standard of patentability, *In re Goodwin*, 198 USPQ 1 (CCPA 1978). Undue experimentation is required in the preparation and use of the proposed combination without Applicant's disclosure.

Claim 1 is directed to an ester formed from a sterol and an omega-3 fatty acid. Therefore, it is clear that the Applicant is claiming a nutritional supplement comprising a sterol ester of an omega-3 fatty acid. Miettinen et al. is directed to a serum cholesterol lowering composition comprising β -sitosterol.

Those skilled in the art understand that the role of the fatty acid moiety of a sitosterol-fatty acid conjugate is to improve its solubility in lipid-based food material. No additional function is generally considered because sitosterol esters are poorly absorbed by the digestive tract. Since omega-3 fatty acids must enter the blood circulation in order to exert an effect

on triglyceride levels, it is not obvious that this will be so when they, in part, form a molecule that is not greatly absorbed. In contrast, the Applicant in the present application teaches that omega-3 fatty acids lower triglyceride levels when provided as a sterol ester.

Leaf et al. does not alleviate the deficiencies of Miettinen et al. Leaf et al. teaches that unesterified omega-3 fatty acids lower serum triglyceride levels. There is no teaching or suggestion in this reference that esterified forms of the omega-3 fatty acids would have the same or similar effect. Changes in the chemical structure of a compound may have profound influence on how the compound behaves in the body. Therefore, it is not obvious to one skilled in the art that an ester (particularly a sterol ester) of an omega-3 fatty acid would have the same or similar triglyceride lowering effect as the omega-3 fatty acid alone.

Since Miettinen et al. appears to teach a way from triglyceride lowering effects of B-sitostanol fatty acid esters, and since there is no basis in Leaf et al. to conclude that esters of omega-3 fatty acids would have a triglyceride lowering effect, one skilled in the art would have no motivation to combine the teachings of Miettinen et al. and Alexander et al. to obtain the claimed invention. The Applicant submits that it is surprising to one skilled in the art that an ester formed from a sterol and an omega-3 fatty acid would retain both the cholesterol lowering effect of the sterol and the triglyceride lowering effect of the omega-3 fatty acid.

The Examiner has also objected to claims 1, 5 to 11, and 30 to 390 as being unpatentable over United States Patent 4,588,717 to Mitchell. The applicant respectfully traverses this objection. Claim 1 has been amended to clarify that the omega-3 fatty acid is derived from a

fish oil. Mitchell discloses esters of sitosterols and fatty acids for use as vitamin supplements. Mitchell particularly discloses the use of fatty acids derived from vegetable oils such as safflower oil, olive oil and corn oil (see, for example, column 7 at lines 27 to 30). Particular examples of individual fatty acids are linoleic acid, linoleic acid and arachidonic acid (see column 7, at lines 30 to 34, and the top of claim 8). Nowhere is there any teaching or suggestion that the fatty acid may be derived from a fish oil. Furthermore, there is no teaching nor suggestion that the fatty acid may be EPA or DHA. In the absence of such teaching or suggestion, the Applicant submits that it would not be obvious for one skilled in the art to make sitosterol esters of fatty acids derived from fish oil, in particular, when the fatty acids are DHA or EPA or mixtures thereof. Furthermore, nowhere is there any suggestion that the sterol esters of fatty acids would have both cholesterol and triglyceride lowering effects. As the Applicant noted earlier, those of skill in the art understand that the role of the fatty acid moiety is to improve the solubility of the conjugate in lipid-based food materials. No additional function is generally considered because sterol esters are recognized by the art to be poorly absorbed by the digestive tract. Thus, the reference to Mitchell provides no motivation to the skilled workman to combine sitosterols and fatty acids derived from fish oils to form an ester which has cholesterol and triglyceride lowering effects. The Applicant submits that in the absence of any teaching or suggestion to use omega-3 fatty acids derived from fish oil, one skilled in the art would find no motivation to combine sitosterols with omega-3 fatty acids derived from fish oil.

Applicant hereby requests reconsideration and reexamination thereof.

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With the above amendments and remarks, this application is considered ready for allowance. Should the Examiner be of the opinion that a telephone conference would expedite prosecution of the subject application, he is respectfully requested to call the undersigned at the below-listed number.

Respectfully submitted,

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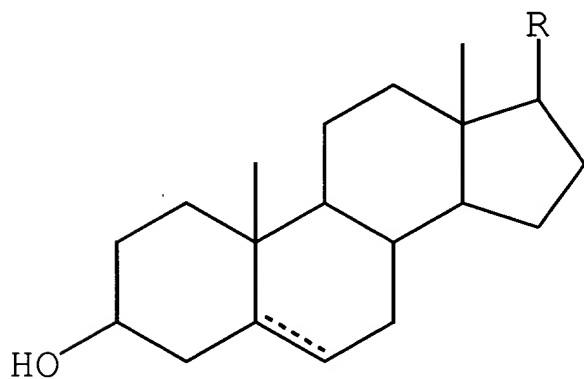


VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (twice amended) A nutritional supplement comprising a sterol ester of an omega-3 fatty acid derived from fish oil, for lowering cholesterol and triglyceride levels in the blood stream of a subject.

38. (once amended) A nutritional supplement comprising a sterol ester of an omega-3 fatty acid derived from fish oil.

39. (once amended) The nutritional [S]supplement of claim 1, wherein the sterol is



where the dashed line is a single or double bond and R is a (C₁-C₁₀) alkyl, [substituted (C₁-C₁₀) alkenyl] substituted (C₁-C₁₀) alkyl, (C₂-C₁₀) alkenyl group or substituted (C₂-C₁₀) alkenyl group.